AACC | Better health through laboratory medicine.

May 19, 2022

Robert H. Campbell, Chair
c/o Susan K. Urahn, President and CEO
Pew Charitable Trusts
901 E Street NW
Washington, DC 20004-2008

Dear Mr. Campbell:

As president of the American Association for Clinical Chemistry (AACC), I request a meeting with your leadership to discuss the role of the Pew Charitable Trusts (Pew) in advancing the VALID Act, and to express our concerns that Pew is spreading misleading information.

AACC has the greatest respect for the Food and Drug Administration (FDA), and we share the agency's goal of ensuring that all in vitro diagnostic devices and laboratory-developed tests (LDTs) are safe and effective. However, FDA is not the best agency to regulate LDTs, as these tests are already regulated by CMS via the Clinical Laboratory Improvement Amendments (CLIA). Any reform of LDT oversight can and should be done through this existing regulatory structure.

Establishing dual FDA-CMS regulation, as the VALID Act would, would only hinder labs' ability to perform LDTs and limit patient access to these essential tests. This ultimately would result in consolidation of the clinical testing market, decreasing competition and patient access to testing alike.

Unfortunately, the VALID Act has been gaining ground, in part because the lay media and some policy circles have presented a "wild west" image of LDTs, depicting them as unregulated tests created by developers who are just out to skirt the system and turn a profit. This image is seemingly grounded in Pew's articles and statements.

We agree with all stakeholders that companies who open reference laboratories and utilize LDTs solely as a business strategy to avoid FDA oversight should not be allowed to operate in this fashion. However, those companies represent a small proportion of the entities providing LDTs, and the answer is not to significantly increase the burden on established clinical laboratories, including academic medical centers, by treating them as if they were device manufacturers. As written and included in the Senate discussion draft of MDUFA, VALID would do just that. The academic medical laboratory community was not part of the discussions around VALID, but we and our patients would suffer significantly if it were to pass in its current form. We need the benefit of time and a seat at the table to help strengthen the regulation of "bad actors" while also preserving patients' access to care.

Furthermore, Pew's writings conflate many of the issues at hand. For instance, Pew cites the unreliable COVID-19 antibody tests that manufacturers developed early on in the pandemic as an example of why FDA regulation of LDTs is needed. However, these antibody tests were not LDTs; they were commercial tests produced by a small number of unreputable diagnostic companies that falsely claimed their tests were authorized by FDA. And while this issue was a major concern, it is completely unrelated to regulation of LDTs, which are only performed internally by the lab or hospital that created them, and are not manufactured, marketed, packaged, or sold to other entities.

Along those same lines, Pew claims that FDA's regulation of COVID-19 tests during the pandemic was a success and uses this to argue that FDA could take on LDT regulation as well. However, in reality, FDA struggled to prioritize new COVID-19 tests for review during the pandemic, raising legitimate concerns about whether FDA has the bandwidth to handle LDT review in a rapid fashion. In fact, had it not been for coronavirus LDTs, the U.S. would never have been able to scale up COVID-19 testing to the levels needed to manage the pandemic.

Perhaps most importantly, the Pew documents ignore the primary role of the medical directors of high-complexity labs, who bear legal responsibility for their performance under CMS. We support vigorous and heightened accountability for these directors, who—along with laboratory owners—provide oversight and resources for successful implementation of laboratory-developed tests. However, as licensed professionals, high-complexity laboratory directors should be permitted to continue their professional practice in providing medical services, which includes the ability to develop and oversee robust, validated laboratory-developed tests.

In general, LDTs are essential in situations where testing must evolve quickly, whether it's in response to a new infectious disease or designer drug. Subjecting these tests to dual FDA-CMS review would only hinder the U.S.'s ability to respond to emerging health threats, as FDA's review process is intended for commercial tests, and is not designed to keep up with new health issues that require immediate action.

Nor is FDA's review process perfect. In its articles, Pew lists only a small number of problems with LDTs, while neglecting to mention all of the times FDA has recalled commercial tests that the agency authorized. This creates the false impression that FDA regulation prevents all of the issues with testing that Pew is concerned about.

Further, in its discussion of companion diagnostics, Pew argues that LDTs may give different answers compared with an initial, FDA-approved companion. While we fully agree that standardization and harmonization are critically important, it is an ironic argument considering not only the large number of FDA-approved tests that are not currently harmonized and do not provide comparable results, but also the notable examples of LDT developers from different laboratories who have worked together to ensure that their results agree.

We also have serious concerns with inferences made in the Pew May 5, 2022, Fact Sheet, "*Americans Support Increased FDA Oversight to Ensure Accuracy of Diagnostic Tests,*" which suggests that perceived public concerns about the quality of laboratory testing would be corrected by VALID and FDA oversight of LDTs. The presentation of the findings suggests LDTs are the problem even though the respondents never specify LDTs as the source of their concern. Further, it appears that the participants in the discussion boards were given pre-determined recommendations, which appear to be selected based on biased information that was designed to lead them to certain conclusions. Given Pew's reputation as a premier research organization, this document is disappointing.

To sum up, speaking on behalf of the laboratory medicine profession, AACC has tremendous respect for the important and high-quality work that FDA performs. However, FDA is not the appropriate agency to regulate LDTs, and any improvements to LDT oversight should be made through CMS and CLIA. We also have great respect for Pew and the role it typically plays as a neutral research organization to help sort through difficult and important issues. We hope you will embrace this role for the issue of LDTs and reverse your current course. Pew is rightfully considered a trustworthy source of information. However, you are currently disseminating incorrect information about this issue, while also ignoring the fact that VALID would have major unintended consequences for the U.S. healthcare system that would significantly impede patient care.

In light of this, I believe it would be beneficial for AACC and Pew's leadership to meet to discuss your support of the VALID Act. I am hopeful that a discussion will allow us to come to a mutual understanding on the subject, and I look forward to your response.

Sincerely,

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